#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Kirvin L. Hodge, et al. Attv. Ref.: 18030-PCTUS

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Appl. No.: 10/531,630 Group Art Unit: 1621

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Conf. No.: 8412 Customer No.: 31976

Title: COMPOUNDS FOR THE TREATMENT OF METABOLIC

DISORDERS

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January 5, 2010

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Attn.: Office of Patent Legal Administration

Sir:

# REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)

This Request for Reconsideration of Patent Term Adjustment is being filed within two (2) months of the issue date of the above-identified patent. And this Request concerns issues that arose after payment of the issue fee. Therefore this Request is timely (37 CFR 1.705(d)). The fee set forth in 37 CFR 1.18(e) is enclosed.

Patentees respectfully request reconsideration of the Patent Term

Adjustment for this patent. The Office determined that the patent is entitled to a

term adjustment of 296 days. The correct term adjustment is not less than 689 days.

#### ISSUE PRESENTED

This patent is entitled to a term extension equal to the sum of: (A) Office delays in taking certain actions; and (B) the amount of time, in excess of three years from the filing date, that it took for the patent to be issued. The Office erred in extending the term only for (A).

## LAW OF PATENT TERM ADJUSTMENT

The term of a patent is extended for the number of days that issuance of the patent was delayed by failures of the Office to promptly take certain actions (35 U.S.C. § 154(b)(1)(A)) ("A delays"). And the term of a patent is extended for the number of days that the Office failed to issue a patent by the three-year anniversary of the date that the application for patent was filed (35 U.S.C. § 154(b)(1)(B)) ("B delay"). The Patent Term Adjustment is calculated by adding the "A delays" plus the "B delay," except to the extent that the periods of delay overlap (35 U.S.C. § 154(b)(2)(A)). "B delay' begins when the PTO has failed to issue a patent within three years, not before." Wyeth v. Dudas, 580 F. Supp. 2d 138, 142 (D.D.C. 2008). Therefore a "B delay" does not overlap with "A delays" that occurred during the first three years that a patent application was pending. Id. at 141.

In this case the Office has calculated the Patent Term Adjustment in accordance with its earlier, contrary "position that . . . the entire period during which the application was pending before the Office . . . and not just the period beginning three years after the actual filing date of the application, is the relevant

period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay 'overlap' under 35 U.S.C. 154(b)(2)(A)." 69 Fed. Reg. 34283 (June 21, 2004). The Office's position is "inconsistent with law" (See 35 U.S.C. § 2(b)(2)) as interpreted by the court in Wyeth.

### "A DELAYS"

The period of adjustment under 37 CFR 1.702(a) is the sum of the following periods:

- (1) "The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application . . . fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of . . . an action under 35 U.S.C. 132. . . . " (37 CFR 1.703(a)(1)). The application entered national phase on April 14, 2005 and the first Office Action was mailed on September 11, 2007. The day after the date that is fourteen months after the application entered national phase was June 15, 2006. And the delay was 454 days, which is the number of days in the period from June 15, 2006 to September 11, 2007.
- (2) "The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of . . . an action under 35 U.S.C. 132. . . ." (37 CFR 1.703(a)(2)). Patentees filed a reply on May 1, 2008 and the next Office Action was mailed on December 22, 2008. The day after the date that is four months after the reply was September 2, 2008. And the delay was 112 days, which is the number of days in the period from September 2, 2008 to December 22, 2008.

(3) "The number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued." (37 CFR 1.703(a)(6)). Patentees paid the issue fee on May 1, 2009 and the patent was issued on November 10, 2009. The day after the date that is four months after the date the issue fee was paid was September 2, 2009. And the delay was 70 days, which is the number of days in the period from September 2, 2009 to November 10, 2009.

The total "A delay" was **636 days**, which is the sum of 454 days plus 112 days plus 70 days.

## "B DELAY"

"The period of adjustment under [37 CFR] § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which . . . the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued. . . ." (37 CFR 1.703(b)).

The patent application commenced national stage on April 14, 2005 and the patent issued on November 10, 2009. The day after the date that is three years after commencement of national stage was April 15, 2008. And the total "B delay" was 575 days, which is the number of days in the period from April 15, 2008 to November 10, 2009.

## CALCULATION OF PATENT TERM ADJUSTMENT

Four hundred fifty-four days of "A delay" occurred during the first three years that the patent application was pending, and 182 days of "A" delay occurred

after the first three years that the application was pending. Accordingly, under *Wyeth*, the period of adjustment due to Office delays is **1029 days**, which is the sum of the 454 days of non-overlapping "A delays" and the 575 days of "B delay."

The period of Office delay is "reduced by . . . the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution" (37 CFR 1.704), which the Office determined to be 340 days. Thus the total Patent Term Adjustment is not less than 689 days, which is 1029 days less 340 days.

The patent is not subject to a terminal disclaimer. 37 CFR 1.703(g).

No fee, other than the fee under 37 CFR 1.18(e), is believed to be necessary in connection with the filing of this paper. If any additional fee is required, the Director is authorized to charge the additional fee to Deposit Account No. 50-1677.

Respectfully submitted,

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